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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,888	07/17/2003	Robert Gurny	4-20437D	7666

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,888	GURNY ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 12-33* is/are pending in the application.

4a) Of the above claim(s) *27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,12-26,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 4-27-2005 is acknowledged.

1. Applicant's arguments with regard to the withdrawal of claims based on the originally presented invention in the reply filed on 4-27-05 are acknowledged. The traversal is on the ground(s) that was as argued on pages 4 and 5 of the response. This is not found persuasive because of the following reasons.

According to the originally presented composition claim 1 (7-17-2003), the solubilizing agent is a polymer, which is resistant to gastric juices and soluble in intestinal juices and the corresponding process claim 9 recites "the solubilizing agent, which is suitable for the formation of an aqueous dispersion of nanoparticles", meaning that the solubilizing agent is the same as in the composition claim 1. However, the process claims (27-31) submitted on 7-2-2004) do not recite any solubilizing agent, but recite a 'hydrophilic polymer' which was not present in the original process claims; the product claim 1 still recites the same solubilizing agent, but does not recite any hydrophilic polymer. The scope of the product claim and the independent process claim are different. The scope of the newly amended claims reciting, "aqueous base further containing polyvinyl alcohol is still different from the amended process claims and the process claims are not dependent from the product claim 1. Furthermore, the requirement of a water-soluble polymer in the composition was not presented in the original claims. Claims 27-31 are still deemed to be a new invention and the requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 1-6, 8, 12-26 and 32-33.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'polyvinyl alcohol has a degree of hydrolysis greater than 70%' as recited in claim 33. What does an alcohol hydrolyze to? Instant specification does not explain this aspect.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-6, 8,12-26 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allemann et al (international Journal of Pharmacology, 1992) of record by itself or in combination with Kawata (4,343,789).

Allemann et al disclose a process of preparation of polymeric nanodispersions containing water soluble polymer (polyvinyl alcohol) and Eudragit S (anionic polymer which is soluble from pH 7 upwards (abstract and page 248). What is lacking in Allemann is the teaching of the use of these nanospheres for encapsulating water insoluble drugs. However, on page 253 Allemann teaches that these nanospheres are

for sustained release dosage forms and therefore, it would have been prima facie obvious to one of ordinary skill in the art to use Allemann's nanosphere dispersions for the water insoluble drugs with a reasonable expectation of success.

As pointed out in the earlier action, Kawata et al disclose fine powders of active agents of low solubility coated with various copolymers of met acrylic acid and methacrylic esters or hydroxypropylmethyl cellulose phthalates. The fine particles are mixed with additives and filled in capsules for oral delivery. The particles can be lyophilized. (Abstract, col. 2, lines 13-44, col. 5, lines 10-20, Examples and claims). One of ordinary skill in the art would be motivated to use Allemann et al's nanodispersons for the delivery of water insoluble drugs with a reasonable expectation of success since Kawata shows the feasibility of enteric delivery of water insoluble drugs using enteric formulations containing water insoluble drugs.

6. Claims 1-6, 8,12-26 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawata et al (4,343,789) by itself or in view of Stainmesse (5,133,908) in further combination with Morella (5,378,474).

Kawata et al disclose fine powders of active agents of low solubility coated with various copolymers of met acrylic acid and met acrylic esters or hydroxypropylmethyl cellulose phthalates. The composition further contain the water-soluble polymer, polyethylene glycol. The fine particles are mixed with additives and filled in capsules for oral delivery. The particles can be lyophilized (abstract, col. 2, lines 13-44, col. 5, lines 10-20, Examples and claims). What is lacking in Kawata et al is the specific teaching

that the powders are of nanoparticles sizes. What is also lacking in Kawata is the teaching of the water-soluble polymer, polyvinyl alcohol.

Stainmesse as discussed in the previous action while disclosing nanoparticles of lipophilic active agents teaches that these nanoparticles can be coated with polymers such as aceto phthalate of polyvinyl, acetophthalate of cellulose (enteric polymers) among others. One of the methods of preparation involves mixing the polymer in an aqueous medium to the active agent in acetone. The particles can be lyophilized (note abstract, col. 2 line 63 through col. 3, line 3, Examples 9 and 15 in particular and claims). It would have been obvious to one of ordinary skill in the art to prepare the nanoparticles of water insoluble drugs and coat them enterically with the expectation of obtaining at least similar results based on the suggestion and guidance provided by Stainmesse.

Morella while disclosing sustained enteric release compositions teaches that polymers such as polyethylene glycol or polyvinyl alcohol can be used as partially acid-soluble component (abstract and col. 9, lines 33-39).

As pointed out above, what is lacking in Kawata et al is the specific teaching that the powders are of nanoparticles sizes. However, assuming that they are not of nano sizes, it would have been obvious to one of ordinary skill in the art to prepare particles of any sizes with the expectation of obtaining intestinal delivery since the site of delivery depends upon the enteric coating and does not depend upon the size of the particles. One of ordinary skill in the art would prepare particles of desired sizes depending upon the purpose for which they are used. One of ordinary skill in the motivated to further to

prepare nanoparticles since the reference of Stainmesse teaches that these particles are used for routine delivery of water insoluble drugs. The use of polyvinyl alcohol instead of polyethylene glycol taught by Kawata would have been obvious to one of ordinary skill in the art with the expectation of obtaining at least similar results since Morella teaches that either of the polymers could be used in sustained enteric release systems.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GSKishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK